

LEAD STABILIZATION DEVICES AND METHODS

Cross- Reference to Related Applications

[001] This application claims the benefit of U.S. Provisional Patent Application No. 60/510,663, filed October 10, 2003, entitled LEAD STABILIZATION DEVICES AND METHODS to Atkinson et al., the entire disclosure of which is incorporated herein by reference.

Field of the Invention

[002] The present invention generally relates to medical devices and methods. More specifically, the present invention relates to medical devices and methods for stabilizing leads in cardiac vasculature.

Background of the Invention

[003] Heart failure is an increasingly common condition worldwide. Cardiac resynchronization therapy (CRT) has shown great promise as a treatment for a large percentage of patients in various stages of heart failure. CRT involves cardiac pacing of both the left and right ventricles of the heart (biventricular pacing), which causes both ventricles to beat simultaneously, greatly improving the pumping efficiency of the heart. Typically, the lead that stimulates the left ventricle is positioned via the coronary sinus into a cardiac vein along the free wall of the left ventricle.

[004] There are numerous challenges in successfully positioning the left ventricular lead, including accessing the coronary sinus and veins, advancing the leads to a position which yields proper stimulation, and preventing subsequent lead dislodgement during removal of delivery devices. Post procedural challenges related to the left

ventricular lead include lead dislodgement prior to fibrosis, loss of stimulation capture, and lead removal necessitated by infection.

[005] Currently available left ventricular leads have generally been designed to facilitate effective delivery and provide fatigue resistance, and are particularly susceptible to dislodgement both intra-procedurally and post-procedurally. Efforts to incorporate more aggressive anchoring into the lead body have generally been insufficient for preventing dislodgment, and/or have compromised effective delivery, fatigue resistance and subsequent lead removal.

Summary of the Invention

[006] Therefore, a need exists to enable effective lead stabilization without compromising lead delivery, resistance to lead fatigue, or lead removal. To address this need, various exemplary non-limiting embodiments are described herein which provide devices and methods for acute and/or chronic lead stabilization. By way of example, not limitation, the lead stabilization mechanisms described herein may be separate from but cooperative with the lead, thus allowing independent delivery and function. To this end, the lead may be designed for effective delivery and fatigue resistance, and the stabilization mechanism may be designed for effective acute and/or chronic anchoring to prevent lead dislodgement. In addition, the stabilization mechanisms described herein may be separable from the lead to permit subsequent lead removal.

Brief Description of the Drawings

[007] Figure 1 is an anterior view of a human heart and associated vasculature;

[008] Figure 2 is a posterior view of a human heart and associated cardiac venous vasculature;

[009] Figure 3 is a schematic side view of a lead and an anchor device in the form of a stent disposed in a cardiac vein;

[010] Figure 4 is a schematic side view of a lead and an alternative anchor device in the form of a stent disposed in a cardiac vein;

5 [011] Figure 5 is a schematic side view of a lead disposed in a coronary vein and an alternative anchor device in the form of a stent disposed in a secondary cardiac vein;

[012] Figure 6 is a schematic side view of an anchor delivery device for use in delivering the anchor devices illustrated in Figures 3 – 5;

10 [013] Figure 7 is a schematic side view of a lead and an alternative anchor device in the form of a coil disposed in a cardiac vein;

[014] Figure 8 is a schematic side view of a lead and an alternative anchor device in the form of a bundle disposed in a cardiac vein;

[015] Figure 9 is a schematic side view of a lead disposed in a cardiac vein and an alternative anchor device in the form of a plug disposed in a secondary cardiac vein;

15 [016] Figures 10 and 11 are schematic side views of a lead and alternative anchor devices in the form of wedges disposed in a cardiac vein;

[017] Figure 12 is a schematic illustration of a release mechanism in the form of a connector cutter;

20 [018] Figure 13 is a schematic side view of a lead disposed in a cardiac vein and an anchor device in the form of a coiled stent disposed near the ostium of the coronary sinus;

[019] Figure 13A is a cross sectional view taken along line A – A in Figure 13;

[020] Figure 13B is side sectional view of the fastener illustrated in Figure 13;

[021] Figure 14 is a schematic side view of a lead disposed in a cardiac vein and an anchor device in the form an anchor catheter; and

[022] Figure 15 is a detailed schematic view of the anchor catheter illustrated in Figure 14.

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Detailed Description of the Invention

[023] The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

10 [024] With reference to Figures 1 and 2, the anatomy of a human heart (H) is illustrated. Figure 1 shows the heart from the anterior side, with the right chambers of the heart shown in section. Figure 2 shows the heart from the posterior side, and illustrates the cardiac veins, including the coronary sinus (CS) and its associated venous branches (great cardiac vein, left marginal vein, left posterior ventricular vein, middle cardiac vein, 15 and small cardiac vein). The CS carries the primary venous return for the cardiac circulation, with the venous branches distributed about the heart and draining into the CS. The CS circumnavigates the left side of the heart, generally between the left atrium (LA) and the left ventricle (LV). The CS drains into the right atrium (RA) at the ostium.

20 [025] Left ventricular leads are typically implanted with the proximal end connected to a pulse generator in a subcutaneous or submuscular pocket, and the distal end (electrode(s)) disposed in one of the cardiac veins to stimulate the left ventricle. The lead body typically extends from the pulse generator in the subcutaneous or submuscular pocket, through the vein wall and into the left subclavian vein (LSV), through the left

brachio-cephalic vein (LBV), down the superior vena cava (SVC) and into the right atrium (RA), into the CS and into the target cardiac vein. The venous circulation is usually accessed by introducing delivery catheters (called guide catheters or guide sheaths) from a venous arteriotomy in the LSV to the CS ostium, following the dashed line shown in Figure 1. Once the CS is cannulated by a delivery catheter, a coronary venogram is obtained to visualize the cardiac veins. The lead is advanced into the CS and the desired cardiac vein, following an exemplary path indicated by the dashed line shown in Figure 2.

[026] There are generally two categories of LV leads, over-the-wire (OTW) leads and stylet-delivered leads. OTW leads incorporate a guide wire lumen which extends through the entire lead body, emerging at the tip of the lead. Navigation within the CS and cardiac veins is performed by advancing a steerable guide wire to a desired location in a cardiac vein, and the lead is then advanced over the guide wire. Stylet delivered leads have a stylet lumen which extends through the lead body, but typically terminates proximal of the distal tip. A shaped stylet is positioned in the stylet lumen and the lead and stylet are advanced together to navigate the lead to a desired location in a cardiac vein.

[027] Once the lead is positioned in a location that yields acceptable stimulation (capture), the delivery catheter is removed. Depending on the particular lead, and the type of electrical connector utilized, removal is accomplished either by withdrawing the delivery catheter over the proximal end of the lead, or by splitting the delivery catheter as it is removed over the proximal end of the lead. In some situations, removal of the delivery catheter may dislodge the lead, as the stability of the lead position is often quite

tenuous. Even if the lead is not dislodged during removal of the delivery catheter, the beating of the heart and other patient activities can cause lead movement or dislodgement, leading to potential loss of capture (effective pacing of the LV).

[028] With reference to Figure 3, a pacing lead 10 and an anchor device in the form of a stent 20 are schematically shown disposed in a cardiac vein CV. Generally, the CV generically refers to venous branches of the coronary sinus such as the great cardiac vein, left posterior ventricular vein, middle cardiac vein, small cardiac vein, or other cardiac vein that leads to the left ventricle, and preferably that leads to the apex of the left ventricular free wall or that otherwise provides for effective pacing of the left ventricle.

5 Those skilled in the art will recognize that because of anatomic variation, the precise name and position of the CV will vary.

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[029] Lead 10 may comprises a conventional pacing lead having an elongate body or shaft 12 and one or more electrodes 14 connected to a pulse generator (not shown) by corresponding wires or traces inside the lead body 12. Lead 10 is generally designed to be very flexible and fatigue resistant to permit free cardiac movement, to minimize tissue trauma, and to withstand repeated flexure primarily caused by the beating heart. The electrodes 14 are typically positioned on or near the wall of the vein facing the heart to establish effective conduction into the heart wall.

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[030] Stent 20 may be self-expandable or balloon expandable, for example, and may be formed of a biocompatible metal material such as stainless steel, Nitinol, Elgiloy, or MP35N. Alternatively, stent 20 may be formed of a biodegradable polymeric material such as poly-L-lactic acid, polyglycolic acid, or polycaprolactone, or other biodegradable materials such as those used for biodegradable sutures. In the case of polymeric

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materials used for stent 20, the polymer may be loaded with a radiopaque agent such as barium, bismuth subcarbonate, etc. to facilitate x-ray visualization. Generally speaking, all of the anchors of the anchor devices described herein may be formed of the aforementioned materials and may be radiopaque.

5 [031] Stent 20 may be connected to lead 10 by an elongate connector 30. Elongate connector 30 may comprise a tether that is flexible and fatigue resistant such as a braided cord of a high strength biocompatible polymer such as polyester, polypropylene, or polyethylene (e.g., Spectra brand), and may be partially or fully covered or coated with a material that promotes tissue in-growth such as ePTFE. The
10 tissue in-growth promoting material may serve to secure the elongate member 30 to the lead 10 and/or prevent bacteria migration along the elongate member 30.

[032] In the embodiment illustrated in Figure 3, the elongate member or tether 30 extends through the lumen (e.g., guide wire lumen) of the lead 10. This embodiment is particularly suitable for OTW leads that typically have a guide wire lumen extending
15 therethrough. The proximal end of the tether 30 may extend out the proximal end of the lumen of the lead 10, and may be connected to the lead 10 by tying a knot that is larger than the diameter of the lumen, for example. Alternatively, the proximal end of the tether 30 may be connected to the proximal end of the lead 10 by trapping the tether 30 in the lumen of the lead 10 with a wedge or pinching it between the electrical connector of the
20 lead 10 and the socket of the pulse generator. The distal end of the tether 30 may be connected to the stent 20 by tying the tether 30 in a knot around a strut of the stent 20, or swaging and end of the tether 30 between struts of the stent 20, for example.

[033] In this embodiment, the stent 20 and tether 30 may be deployed before the lead 10 is delivered. The stent 20 may be deployed in a distal portion of the target CV with a delivery device as described in more detail with reference to Figure 6. Once deployed, the proximal end of the tether 30 may be inserted into the distal end of the 5 lumen extending through the lead 10, and the lead 10 may then be advanced over the tether 30 and into the CV to the desired position, and pacing tests may be performed to ascertain LV pacing capture. Once the lead 10 is in the desired position, the proximal end of the tether 30 may be secured to the proximal end of the lead 10 as described previously.

10 [034] If it is necessary or desired to remove or reposition the lead 10, the lead 10 may be removed from the CV by disconnecting the tether 30 from the lead 10 (e.g., by cutting the knot in the tether 30 at the proximal end of the lead 10), the tether 30 may be removed from the CV by disconnecting the tether 30 from the stent 20 (e.g., by using a cutting device as described in more detail with reference to Figure 12), and the stent 20 15 may be left in place in the CV without compromising blood flow through the CV.

[035] With reference to Figure 4, an alternative anchor device arrangement is shown schematically. In this embodiment, rather than extending through the lumen of the lead 10, the tether 30 extends along side the lead 10. This embodiment is particularly suitable for stylet-delivered leads that typically do not have a lumen extending 20 therethrough, but may be used with either stylet-delivered or OTW leads. This embodiment also allows for the delivery of the anchor device either before or after lead 10 placement.

[036] The tether 30 may be connected to the lead 10 by a fastener such as collar 40. Collar 40 may comprise a short dual lumen tube including a relatively large lumen to accommodate the lead 10 therethrough and a relatively small lumen to accommodate the tether 30 therethrough. Collar 40 may be fixedly connected to the lead 10 if the anchor device is delivered prior to the lead 10 by swaging, adhesive, etc. To facilitate delivery of the lead after placement of the lead 10, the collar 40 may be slidable over the lead 10 and lock in place adjacent the distal portion of the lead 10 using a mating geometry such as a detent on the outer surface of the lead 10 that receives a protrusion extending from the inside surface of the collar 40. Alternatively, the outer surface of the lead 10 may include a protrusion such as a stepped ridge 45 that abuts the distal end of the collar 40 as the collar 40 is advanced over the lead 10 in order to prevent proximal movement of the lead 10 relative to the collar 40. With this alternative, the stepped ridge 45 may be an integral extension of the outer surface of the lead 10 or a separate component fixedly connected to the lead 10.

[037] The tether 30 may be effectively connected to the collar 40 to prevent proximal movement of the collar 40 relative to the tether 30 by utilizing a knot or stop 35 that is slid down the length of the tether 30. A knot may be made in the tether at its proximal end and advanced distally to the collar 40 using a conventional knot pusher. A stop 35 may be used and configured to readily advance distally over the tether 30 and resist retraction proximally. For example, stop 35 may comprise a short tubular segment having proximal facing flanges extending from the inside surface that selectively engage the tether 30 only when the stop 35 is advanced in the proximal direction relative to the tether 30. To facilitate removal of the lead 10, the stop 35 may be cut or the tether 30

may be cut between the stop 35 and the collar 40 using the cutting device described with reference to Figure 12.

[038] To facilitate advancement of the collar 40 over the lead 10 and to facilitate advancement of the stop 35 over the tether 35, a dual lumen advancement sheath 50 may 5 be slid (pushed) over the lead 10 and tether 30. Sheath 50 may comprise an elongate dual lumen tube having a length sufficient to extend over the lead 10, through the venous vasculature, and out the venous access site, with one lumen to accommodate the lead 10 and another lumen to accommodate the tether 30. Sheath 50 may include a slit (not shown) along the length thereof to facilitate peeling over the lead 10. Sheath 50 may be 10 removed over the lead 10 and tether 30 after advancement of the collar 40 and stop 35, or it may be left implanted to contain the tether 30 relative to the lead 10.

[039] With reference to Figure 5, an alternative anchor device arrangement is shown schematically. In this embodiment, the stent 20 is deployed in a secondary cardiac vein (SCV) and connected via tether 30 and collar 40 to lead 10 as described with 15 reference to Figure 4. Positioning the stent 20 in a SCV enhances the anchoring effect and, because of collateral venous circulation, reduces the possibility of adverse effects if the stent 20 were to become occluded.

[040] With reference to Figure 6, a schematic side view of an anchor delivery catheter device 100 for use in delivering anchor devices such as stent 20 as described in 20 connection with the embodiments of Figures 3 – 5. In this embodiment, the delivery device 100 is configured to deliver an elastically expandable (self-expanding) stent, but a balloon catheter type delivery device may alternatively be utilized to deliver a plastically deformable (balloon expandable) stent. In the illustrated embodiment, the delivery

catheter 100 may include an inner tube 110 coaxially disposed in an outer tube 120. The stent 20 may be pre-loaded inside the outer tube 120, near its distal end. The distal end of the inner tube 110 abuts the proximal end of the stent 20, and may be advanced distally with respect to the outer tube 120 as indicated by arrow 115 to advance stent 20 out of the 5 distal end of the outer tube 120. The tether 30 may be disposed between the inner tube 110 and the outer tube 120.

[041] To facilitate delivery, a guide wire 130 may be used to initially navigate the CV. Once the guide wire 130 is in the desired position, the delivery catheter 100 with the pre-loaded stent 20 therein may then be advanced over the proximal end of the guide 10 wire 130 and advanced thereover to the desired deployment position. The inner tube 110 may be advanced in the distal direction with respect to the outer tube 120 as indicated by arrow 115 to deploy the stent 20 in the CV. Once the stent 20 is deployed, the delivery catheter 100 may be removed.

[042] With reference to Figure 7, an alternative anchor device arrangement is 15 shown schematically. In this embodiment, a coil 70 is deployed distal of the lead 10 and connected via tether 30 to lead 10 as described with reference to Figure 3. The proximal end of the coil 70 may be connected to the distal end of the tether 30 at connection 75, and the coil 70 may comprise a resilient structure such as a metal wire formed of any of the materials described with reference to stent 20. Coil 70 may be delivered via a lumen 20 (e.g. guide wire lumen) extending through the lead 10 and is particularly suitable for an OTW lead. The coil 70 may be advanced through the lumen of the lead 10 using a push tube (not shown) having sufficient column strength disposed over the tether 30 that abuts the connection 75 between the coil 70 and the tether 30.

[043] To accommodate delivery through the lumen extending through the lead 10, the coil 70 may have a delivery configuration wherein the coil 70 is elongated to have a reduced profile sufficiently small to fit into the lumen, and a deployed configuration wherein the coil 70 is radially expanded to have an expanded profile sufficiently large to 5 frictionally engage the wall of the CV. The coil 70 may be highly elastic such that it assumes the deployed configuration automatically upon advancement out of the distal end of the lead 10, or the coil may be actuated (e.g., thermally) upon advancement out of the distal end of the lead 10 to assume the deployed configuration.

[044] With reference to Figure 8, an alternative anchor device arrangement is 10 shown schematically. In this embodiment, a bundle 80 is deployed distal of the lead 10 and connected via tether 30 to lead 10 as described with reference to Figure 3. The proximal end of the bundle 80 may be connected to the distal end of the tether 30 at connection 85, and the bundle 80 may comprise a resilient structure such as a metal wire formed of any of the materials described with reference to stent 20. Bundle 80 may be 15 delivered in the same manner as and may have the same or similar characteristics as coil 70 described with reference to Figure 7. Bundle 80, as opposed to coil 70, may have an occlusive effect, and therefore may be particularly suitable for a SCV to take advantage of collateral venous circulation.

[045] With reference to Figure 9, an alternative anchor device arrangement is 20 shown schematically. This embodiment is similar to the embodiment illustrated in Figure 5, except that a plug 90 is used in place of stent 20. The plug 90 may comprise a curable adhesive (e.g., cyanoacrylate, EVA in a DSMO solvent) or an embolic coil, for example, such as those conventionally used in occluding blood vessels and aneurisms. Plug 90

may be deployed in a SCV using a conventional embolic delivery system and connected via tether 30 and collar 40 to lead 10 as described with reference to Figure 4. Positioning the plug 90 in a SCV enhances the anchoring effect, and despite the occlusive effect of the plug 90, the possibility of adverse effects are reduced if not eliminated due to
5 collateral venous circulation.

[046] With reference to Figures 10 and 11, alternative anchor device arrangements are shown schematically. In these embodiments, a wedge 140 or 150 is deployed adjacent the distal portion of the lead 10, such as proximal of electrodes 14. Wedges 140 and 150 frictionally engage the lead body 12 and the wall of the CV, to
10 lodge the lead 10 in the desired position in the CV. The wedges 140 and 150 may be connected to tether 30 to facilitate subsequent removal. Wedges 140 and 150 may comprise any of the materials discussed with reference to stent 20. Wedges 140 and 150 are particularly suitable for deployment after the lead 10 has been delivered to the desired position.

15 [047] With specific reference to Figure 10, wedge 140 includes a body portion 142 and optional threads 144. Body portion 142 may include a perfusion lumen extending therethrough to permit blood perfusion from the distal end to the proximal end of the wedge 140. The wedge body 142 (or the wedge threads 144 if used) may have a diameter slightly greater than the diameter of the lumen of the CV less the diameter of the
20 lead 10 in order to provide a snug frictional fit therebetween. Wedge 140 may be delivered into the desired position utilizing a push tube 60 advanced over a guide wire (not shown), for example, wherein the push tube 60 has sufficient column strength to push the wedge 140 alongside the lead 10 with the distal end 65 of the push tube abutting

the proximal end of the wedge 140 and the tether 30 extending through the push tube. The push tube may also have sufficient torsional strength with a distal end 65 that mates with the proximal inside diameter of the wedge 140 such that the wedge 140 may be rotated to engage or disengage the threads 144 with the lead 10 and the wall of the CV.

5 [048] With specific reference to Figure 11, wedge 150 comprises a short dual lumen having one lumen to accommodate the lead 10 and another (crescent shaped) lumen to permit blood perfusion from the distal end to the proximal end of the wedge 150. The wedge 150 may be tapered and may have a diameter slightly greater than the diameter of the lumen of the CV less the diameter of the lead 10 in order to provide a
10 snug frictional fit therebetween. Stepped ridge 45 prevents proximal movement of the lead 10 relative to wedge 150 as described previously. Wedge 150 may be delivered into the desired position utilizing a push tube 50 advanced over the lead 10, as described previously.

[049] With reference to Figure 12, a cutting device 160 is shown schematically.
15 Cutting device 160 may be used to cut tether 30 and/or stop 35 in order to disconnect the tether 30 from the anchor device, such as stent 20. Cutting device 160 is merely an example of a variety of cutting mechanisms that may be used to sever the connection of the tether 30 from the anchor device. For example, the tether 30 may be equipped with two internal wires connected to a distal electrolytic fuse that separates (melts) upon the
20 application of electrical current, such as those used for detachable embolic coils.

[050] In this exemplary embodiment, cutting device 160 includes an outer tube 162 and an inner tube 164 coaxially disposed and movable therein. The outer and inner tubes 162 and 164 may have a length sufficient to extend from outside the vascular

access site to the anchor device, and may be configured for intravascular navigation and advancement over tether 30. The distal end of the inner tube 164 may have a sharpened edge and may be formed of a material that retains a cutting edge (e.g., metal). A cutting hole 168 is provided adjacent the distal end of the outer tube 162 through which the tether 5 30 may be threaded. The distal circumference of the cutting hole 168 may be sharpened and may be formed of a material that retains a cutting edge (e.g., metal) After the cutting device is advanced over the tether 30 to the desired cutting site, the inner tube 164 may be advanced distally as indicated by arrow 166, with the sharpened distal end of the inner tube 164 and the sharpened cutting hole 168 acting as shears to cut the tether 30 at the 10 cutting hole 168.

[051] With reference to Figure 13, a lead 10 is shown disposed in a CV, with an anchor device in the form of a coiled stent 200 disposed near the ostium of the CS. The coiled stent 200 may be positioned near the ostium of the CS, where the vessel diameter is large enough to resist becoming occluded by the presence of the coiled stent 200 next 15 to the lead 10. However, it is contemplated that the coiled stent 200 may be placed elsewhere within the CS or CV in which the lead is positioned. As seen in Figure 13A, the lead 10 is eccentrically disposed in the lumen of the CS to define a relatively large crescent shaped blood perfusion lumen.

[052] Coil stent 200 may be formed of a resilient material such as Nitinol, 20 Elgiloy, MP35N, or stainless steel. Coiled stent 200 could also be formed of degradable materials such as those described in reference to stent 20 above. Coiled stent 200 may be releasably attached to the lead 10 utilizing collar 210, and collar 210 may frictionally

engage the body 12 of lead 10, thus facilitating anchoring of the lead within the coronary sinus or cardiac vein.

[053] With reference to Figure 13B, the collar 210 may comprise a relatively short tube 212, and may include one or more proximally oriented grips 218. Grips 218 5 may be in the shape of finger-like projections, or circular ribs either partially or completely extending circumferentially around the inside of tube 212. Grips 218 facilitate the advancement of the collar 210 in a distal direction for delivery over lead 10, but resist proximal movement once the collar 210 is positioned in a desired anchoring location. Grips 218 may be formed of a soft resilient material such as silicone, 10 polyurethane, polyether-block-amide, or the like.

[054] To facilitate subsequent removal of the lead 10, the coiled stent 200 may be connected to the collar 210 in a detachable manner. For example, the coiled stent 200 may be connected to the collar 210 utilizing a biodegradable adhesive connecting adjacent portions of the coil 200 to the collar 210. Such an adhesive may degrade after 15 the lead 10 has chronically anchored to the wall of the CS by normal tissue encapsulation. After the adhesive has degraded, the lead 10 (along with collar 210) may be removed utilizing standard techniques, with the coiled stent 200 remaining in the CS.

[055] Alternatively, the coiled stent 200 may be secured to the collar 210 utilizing a retractable pin 220. In this alternative embodiment, collar 210 may include 20 two angled flanges 214 collectively defining a recess 216 in which stent coil 200 may reside. Pin 220 may span the length of the recess 216 between the flanges 214, extending over the coiled stent 200 to retain the coil stent 200 in the recess 216, thus providing a connection between the stent coil 200 and the collar 214. Subsequent release of the stent

coil 200 from the lead 10 may be accomplished by removing pin 220 using tether 30 which extends from the proximal end of the lead 10 to the pin 220. The proximal end of the pin 220 is connected to the distal end of the tether 30, and the pin 220 may be removed by pulling the tether 30 proximally. After the pin 220 is removed, the lead 10
5 and collar 210 are free from the stent coil 200 and may be removed with standard techniques, leaving stent coil 200 in the CS.

[056] Delivery and deployment of the stent coil 200 and collar 210 may be facilitated by deployment sheath 230. The deployment sheath 230 may comprise a tubular catheter, having a lumen extending therethrough to accommodate the lead 10 and
10 the stent coil 200. Alternatively, the lumen in the deployment sheath 230 may extend from a distal opening to a mid-shaft opening as used in conventional monorail style balloon catheters. After lead 10 has been positioned by standard techniques to a desired position, the stent coil 200 and collar 210 may be loaded on the proximal end of the lead
10. Coil 200 may be initially in a compressed condition, and loaded in the inside of the
15 deployment sheath 230. If the lead 10 has a large diameter proximal connector, an optional slit 215 may be provided in the collar 220 to facilitate loading over the large diameter connector. In this case, the collar 210 and coil 200 may be positioned on the lead body 12 before the coil 200 is loaded into the deployment sheath 230. The deployment sheath 230 may be advanced distally down the body 12 of the lead 10 until
20 the stent coil 200 and collar 210 are in the desirable location. The deployment sheath 230 may then be withdrawn proximally, with the collar 210 and stent coil 200 remaining in position on the lead 10 due to grips 218 on collar 210. As the stent coil 200 emerges

from the deployment sheath 230, it expands to engage the wall of the CS. The deployment sheath 230 can then be removed from the lead 10.

[057] Figures 14 and 15 illustrate an anchor device in the form of an anchoring catheter 300, which may be utilized to secure the position of lead 10, particularly during 5 the removal of the guide sheath (guide catheter) used in the delivery of the lead 10. As described above, the lead stability is particularly vulnerable during the removal of the guide sheath.

[058] In use, the anchoring catheter 300 is positioned next to the lead 10 after lead 10 has been positioned in a desired location. Anchoring catheter 300 may be 10 advanced within the guide sheath (not shown), generally parallel to the lead body 12, or may be advanced outside the guide sheath. An expandable member such as a balloon 314 is inflated to frictionally secure lead 10 against the wall of the blood vessel. The guide sheath can then be removed without inadvertent dislodgement of the lead 10. The anchoring catheter 300 can then be removed. Since anchoring catheter 300 is next to and 15 not surrounding the lead body 12, removal of the anchoring catheter 300 does not pose a risk of dislodging lead 10.

[059] With particular reference to Figure 15, anchoring catheter 300 is shown in more detail. Shaft 312 may comprise a proximal shaft portion 312A connected by adhesive, for example, to a distal shaft portion 312B. A luer adaptor 316 may be 20 connected to the proximal end of the proximal shaft portion 312A for connection to an inflation apparatus (not shown) such as a syringe. An inflatable balloon 314 may be connected to the distal end of the distal shaft portion 312B, and may be formed of elastomeric material or a molded inelastic material.

[060] Proximal shaft portion 312A may be relatively stiff and may be formed of a metallic tube such as a stainless steel hypotube. Distal shaft portion 312B may be relatively flexible and may be formed of a polymeric tube, for example. To facilitate advancement of the flexible distal shaft portion 312B and the balloon 314, a core wire 5 may be connected to and extend from the distal end of the proximal shaft portion 312A. The core wire 320 may comprise a metal wire such as a tapered stainless steel mandrel.

[061] Core wire 320 extends to the distal end of the balloon 314, and may extend beyond with an atraumatic spring tip, for example. The distal end of the balloon 314 may be bonded to the core wire 320, and the proximal end of the balloon 314 may be 10 bonded to the distal end of the distal shaft portion 312B. Within the shaft 312 is a lumen through which inflation medium is infused to inflate balloon 314.

[062] Those skilled in the art will recognize that the present invention may be manifested in a variety of forms other than the specific embodiments described and contemplated herein. Accordingly, departures in form and detail may be made without 15 departing from the scope and spirit of the present invention as described in the appended claims.